

**510(k) Summary of Safety and Effectiveness****Submitter Information:**

Rozinn Electronics Inc.  
71-22 Myrtle Ave.  
Glenside, NY 11385-7254  
Phone: 718-386-5526  
Contact: Mark Rosoff, President

**Product Name:**

Proprietary: Holter Plus™ Ambulatory ECG Analysis System  
Common: Programmable Diagnostic Computer and Software.  
Classification: Class II (see 21 CFR - 870.1425)

**Predicate Devices:**

The predicate device(s) are the following:

1. Northeast Monitoring Inc. Holter for Windows System (510(k) K930564).
2. Caird Technology Holter 2000 System. (510(k) K012686).
3. Advanced BioSensor ABS Holter (formerly Micro SI Ambulatory ECG Monitor) System (510(k) K881905).
4. Oxford Scientific Medilog Excel 2 System. (510(k) K002544).
5. Biomed Systems Inc. WinPV Holter System. (510(k) K8841524).

These predicate devices have the same performance specifications as the Holter Plus™ Ambulatory ECG Analysis System

**Device Description:**

The Holter Plus™ Ambulatory ECG Analysis System is an ambulatory ECG analysis system comprised of a standard computer display, a standard Personal Computer (PC) based system, and hardware used to acquire the ambulatory ECG data (specifically the Braemar RZ153+ data recorder – 510(k) K993618). The Holter Plus™ Ambulatory ECG Analysis System can provide the retrospective display, storage and recording (or printing) of ambulatory ECG waveform and annotated data that is provided by the Braemar RZ153+ recorder.

The Holter Plus™ Ambulatory ECG Analysis System allows the assessment and review of a patient's recorded ambulatory ECG records, and presents an analysis for the clinician's review and editing. This product performs a high-speed analysis of the data, classify the data into appropriate ECG morphologies, and allow the results to be printed if desired. The Holter Plus™ does not perform any diagnosis of data, but only displays the

ECG morphologies, and associated curves calculated from the data such as heart rate trends and RR variability in graphical form. The physician will be able to review, edit, and print the data collected. The Holter Plus™ will provide information such as when patient-activated events occurred.

The Holter Plus™ Ambulatory ECG Analysis System provides storage of patient data for archiving and printing various reports. This includes waveform and patient parameter data for the ambulatory ECG data and assessment. The waveform and parameter data that has been stored in a patient file can be retrieved and reviewed on the display or printed out on a laser printer.

### **Intended Uses:**

The Holter Plus™ Ambulatory ECG Analysis System is intended for general hospital or clinical use by medical professionals whenever it is required to assess a patient's ambulatory ECG data. This product allows a trained physician or health care professional, after having performed a long-term continuous electrocardiograph (ECG) recording on a digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports. This will enable the evaluation of arrhythmias, ischemic attacks, reporting of PQRS intervals, clinical and epidemiological research studies, evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery, and/or evaluation of patients with pacemakers.

The need to record, review, edit and archive these ambulatory ECG data is most commonly encountered in the Cardiology areas of the hospital during cardiac patient assessment. This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications.

### **Technological Comparison to Predicate Device(s):**

The Holter Plus™ Ambulatory ECG Analysis System uses the same type of technology (i.e. personal computers and Microsoft Windows-based data analysis software) that is found in the predicate devices listed above.

### **Summary of Performance Testing:**

Tests demonstrating ambulatory ECG testing equivalence with the predicate devices listed above has been performed, and these results show similar performance with these devices.

Conformance to the product development procedures and plans have been assured by the application of the system tests, design reviews, and product verification and validation testing performed prior to product release.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 22 2004

Rozinn Electronics, Inc.  
c/o Mr. Robert Mosenkis  
President  
Citech  
5200 Butler Pike  
Plymouth Meeting, PA 19462-1298

Re: K042463  
Trade Name: Holter Plus™ Ambulatory ECG Analysis System  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: Class II (two)  
Product Code: DQK  
Dated: September 10, 2004  
Received: September 13, 2004

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Holter Plus

Indications for Use:


The Holter Plus™ Ambulatory ECG Analysis System is intended for general hospital or clinical use by medical professionals whenever it is required to assess a patient's ambulatory ECG data. This product allows a trained physician or health care professional, after having performed a long-term continuous electrocardiograph (ECG) recording on a digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports. This will enable the evaluation of arrhythmias, ischemic attacks, reporting of PQRST intervals, clinical and epidemiological research studies, evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery, and/or evaluation of patients with pacemakers.

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Prescription Use X Over-The Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K042463

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